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October 20th, 2003

Dr. Andrew Rawicz
School of Engineering Science
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Re: ENSC 340 Functional Specification for a Small Heart EKG

Dear Dr. Rawicz:

Attached with this letter is the *Functional Specification for a Small Heart EKG* which is previously described in the proposal. We are developing a Small Heart EKG that will record electrical signals from a heart's surface to analyze irregular heart pulses in infants due to arrhythmias.

The requirements and goals of our product are specified here in our functional specification. The specification for individual phases, components, as well as the final prototype will be featured. Each item is categorized into priorities during development of the product.

Avrio Medical Inc. consists of six experienced and hard working fourth-year and fifth-year engineering students who love to incorporate knowledge to aid people: Jeff Chang, Eric Chow, George Kwei, Seddrak Luu, Joe Ma and Kenny Pak. Please contact us if there are any questions or concerns via email, ensc340-wireless@sfu.ca or by phone through Seddrak Luu at 604-719-5929. Thank you.

Sincerely,

Seddrak Luu

Seddrak Luu
Chief Executive Officer
Avrio Medical Inc.

Enclosure: *ENSC 340 Functional Specification for a Small Heart EKG*

Functional Specification for a Small Heart EKG

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Date:

October 6th, 2003

Executive Summary

Open heart surgery that corrects congenital heart disease found in new born children can result in a series of complications. According to the BC Children's Hospital, one in ten children who have open heart surgery will encounter some form of medical complication. One of the more severe, sometimes lethal, complications is an arrhythmia unique to children known as Junctional Ectopic Tachycardia (JET). These young patients will enter a phase where they have an irregular rhythmic beating of their heart, leading to potentially lethal complications.

Hospitals may charge up to twenty thousand dollars per day in the Intensive Care Unit (ICU) and patients of JET may need to stay in excess of twenty days. More serious JET symptoms will lead to almost immediate death. As a result, there is a need for a system that will obtain electrical signals from the heart surface in a cost efficient way. These signals can then be analyzed by cardiologists to further aid the study of JET towards the ultimate goal of understanding why such irregular rhythmic beatings of the heart occur.

Avrio Medical Inc. (AMI) will produce a reliable high resolution cardiac mapping and analysis system, the *Avrio Small Heart EKG*. In this task, we are committed to achieve and reach international standards. Four phases are involved with the development of the product: the signal retrieval phase, the signal transmission phase, the signal processing stage and the signal analysis stage.

To ensure the reliability of our product, an exclusive test plan is designed with Food and Drug Association (FDA) and international standards in mind. In addition, two sets of internal design standards will be met. The first standard will enable us to accomplish the basic requirements of each of the four phases. These include retrieving a signal in the micro-volt range, isolating the electrical heart signals from extraneous noise, and to safely transmit the electrical heart signals to a monitor display. The second standard is to reduce signal distortion by keeping the number of wires connecting each phase to a minimal. The projected goal and timeline for the first set of standards will be achieved by mid-November, while the second set of standards will follow and be achieved by mid-December.

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List of Tables and Figures

Abbreviations

AAMI: Association for the Advancement of Medical Instrument
A/D: Analog to Digital
AMI: Avrio Medical Inc.
ANSI: American National Standard Institute
ASH: Asymmetric Septal Hypertrophy
AV: atrioventricular
BCRI: British Columbia Research Institute
CSA: Canadian Standards Associations
DAQ: Data Acquisition
EKG: Electrocardiogram
FDA: Food and Drug Association
IEC: International Electrotechnical Commission
IEEE: Institute of Electrical and Electronics Engineers
JET : Junctional ectopic tachycardia
SA: Sinoatrial
UL: Underwriters Laboratories, Inc.

1. Introduction

The *Avrio Small Heart EKG* is specifically designed to be used on small hearts, such as that of an infant. It should be noted, however, that prototype testing will be performed on the heart of rabbits. The *Avrio Small Heart EKG* uses custom built electrodes to effectively pick up weak electrical signals from a heart surface, and display an amplified, filtered, and analyzed version on a computer. Currently, the *Avrio Small Heart EKG* will be most widely used in a research setting to aid cardiologists understand arrhythmias in infants.

The system will be developed in 3 phases, signal retrieval, signal transmission, and signal processing/analysis. Each phase is an essential part of the complete design, and will be tested carefully to ensure the accuracy and reliability of the system.

The ultimate goal for Avrio Medical Inc. (AMI) is to develop a high resolution cardiac mapping system to detect the JET arrhythmias. Included in the functional specification is a section on the related regulations both in Canada and United States to bring a medical device to market.

1.1 Intended Audience

This document is intended to be a design guideline for engineers within the AMI. Its purpose serves as ensuring that the product developed by AMI meets the specified requirements. Marketing will use this document to arrange sales strategies. Any descriptions mentioned in this document will be protected as AMI's intellectual property.

1.2 Conventions

The reference numbers denote the requirement of the product and will precede as

RN-[*x*-*y*]

RN = short for Requirement Number
x = Requirement Number
y = either denotes by:
- *n* = necessary requirement in both initial and final prototypes
- *g* = proof of concept and may implement in the final prototype

2. System Overview

Figure 1 (Section 4) shows a system overview of the *Avrio Small Heart EKG*. The natural electrical signals of a heart propagated from the top of the heart to the bottom.

To collect and record the electrical heart signals, a 1.0cm x 1.5cm (9-pin/channel) electrode array grid will be placed onto the surface of the isolated rabbit heart. This electrode array will follow and record the intensity of the electrical signal propagation traversing the heart.

The electrode array will relay the heart's electrical signals to the Preamplifier and Filtering Module (PFM). The PFM will be responsible for increasing the signal strength and cleaning up any noise present.

Next, with a clean amplified signal, the rabbit heart's electrical information will be sent to a Digital Data Acquisition (DAQ) System. The DAQ will be responsible for converting the analog signal to a digital medium and performing all the necessary signal processing. The digital signal will be run through a set of in house developed analysis programs under the Labview program on the PC platform which will analyze the spectral patterns to diagnose the causes which cause JET syndrome.

Finally, a Data Display Unit will output all the recorded and analyzed data into an easily interpretable graphical display.

3. Foundations and Expectations

3.1 System Input Requirement

Our system has been designed to fit a small heart (i.e. rabbit) in all sizes and dimensions.

- Average weight: 1 gram
- Dimensions: 2 cubic centimeters

The expected signals across this extremely small heart from the SA to AV nodes are expected to be in the high micro-volt range while the signal noise picked up by our electrodes can be in the high milli-volt range. We will need to design in a way to filter this noise out.

The current rabbit heart in which we will be doing our system testing upon will have chemicals being injected into the left atrium and out of the left ventricle. These chemicals are used to simulate the same conditions the heart would be in if inside the rabbit body so that it can beat/pump on its own.

The testing and application environment in which we will be using our system device will be within a laboratory setup. We will need to take this into consideration as we design our system due to the limited space we will be working in. This limited area is unavoidable due to the fact of the chemical equipment that is necessary to get the heart to beat so that our device can sense the electrical spectrum in which we are attempting to observe.

4. Overall System Requirement

The specifications for the whole systems are listed below in Figure 1. In order to guarantee a realistic model, the *Small Heart EKG* has to be compatible with the environmental parameters, as well as reliability considerations. Individual requirements are illustrated in section 5. Figure 1 shows the general structure of the *Small Heart EKG*.

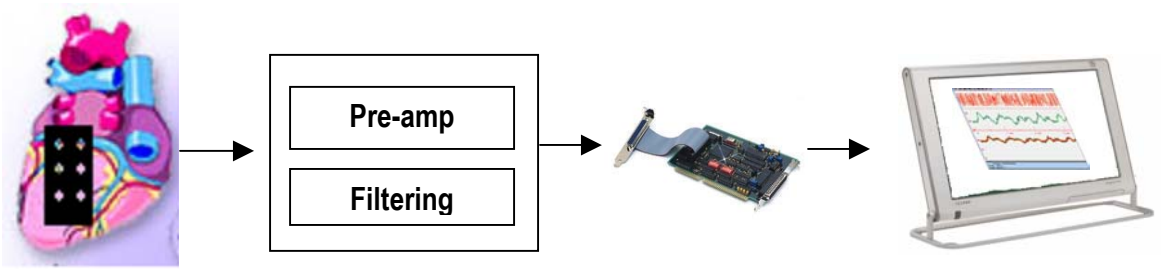


Figure 1: General Components of the Small Heart EKG

4.1 Physical Requirements

The *Small Heart EKG* must satisfy the following physical requirement in order assure the system to work.

RN-[1-n] The unit should be attached to the input in the shortest distance possible
RN-[2-n] The electrode array for input must be small enough to capture signals in the correct area of the heart.
RN-[3-n] Power applied to the unit should be as far away from the heart as possible.

4.2 Environment Requirements

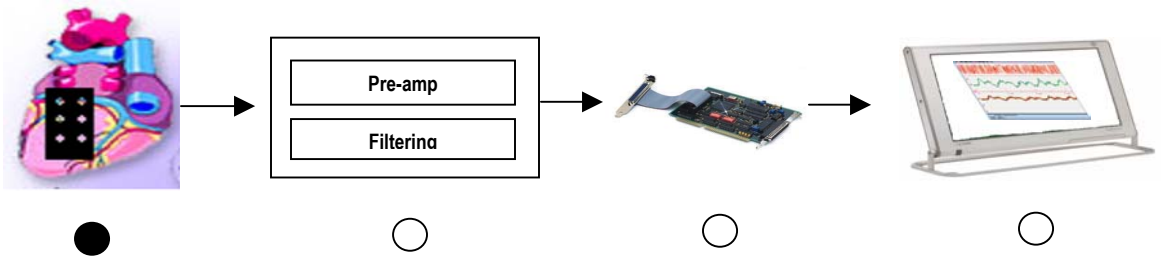
RN-[4-n] The system will be operating at all humidity and pressure ranges normal to internal standards of a human being.
RN-[5-n] The unit, excluding the A/D and signal display, is able to operate between room temperature to normal infant and rabbit body temperature.

4.3 Reliability and Serviceability

RN-[6-n] The electric grid is sufficiently mounted and is flexible.
RN-[7-n] The system is able to pick up micro voltage range signal as long as the electrode array is correctly placed on the heart.
RN-[8-n] Must be repeatable. The system traces the same signal at the same area given the situation is constant.

5. System Requirement

5.1 Electrodes Grid Requirements



The *Avrio Small Heart EKG* will be using surface electrodes. There are essentially 2 types of surface electrodes, dry electrodes and gelled electrodes. However, dry electrodes are not suitable to the application of rabbit's heart because they are considerably heavier than gelled electrodes (>20g), while the rabbit's heart is only 1g in size and can not possible hold something 20 times it's weight. Therefore, gel electrodes will be used, and will be discussed in this functional specification. Gelled electrodes use an electrolytic gel as a chemical conductive interface. The gel also serves as adhesive to hold on to the skin or in this case the outer wall tissue of the heart.

The *Avrio Small Heart EKG* uses custom made electrodes. Following industry guidelines will be important in constructing a successful and reliable electrode. The SENIAM initiative (www.rrd.nl/projects/content/fil_100.htm, Freriks and Hermens, 2000) has a few recommendations for constructing electrodes.

- Electrode shape
- Electrode size
- Inter-electrode distance
- Electrode material
- Electrode construction

The design and construction of the electrode array is the most crucial part of the system. Without an accurate and reliable electrode array, the *Avrio Small Heart EKG* will not be possible.

5.1.1 General Requirements

RN-[9-g]	The grid of electrodes must follow the contour of the heart to gain the most reasonable signal spectrum.
RN-[10-n]	Size must be large enough to fit 9-12 wires
RN-[11-g]	Electrodes must be as far apart as possible in the given area.
RN-[12-n]	Use inert materials for electrode gel.
RN-[13-g]	Use inert but conductive materials for wire, like platinum and gold.
RN-[14-n]	The wires must be well attached to the gel and body of the electrode

RN-[15-n] Minimal movement of the wires when heart is pumping
RN-[16-g] A flexible housing for the electrodes

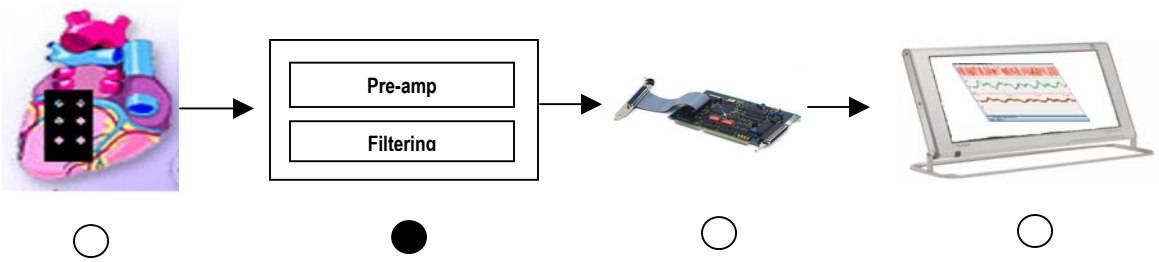
5.1.2 Physical Requirements

RN-[17-g] Surface area for each electrode site should be the same and must fit the overall heart.
RN-[18-n] Must be confined in a 10mm X 15mm space in size.
RN-[19-n] Must have 2 mm between each electrode wire.
RN-[20-n] Must be small and light
RN-[21-g] Total weight must be less than ½ of the heart
RN-[22-n] Wires must be covered with gel
RN-[23-n] Insulation is necessary to block off interferences between wires
RN-[24-g] Only tips of the wire contact the heart

5.1.3 Performance Requirements

RN-[25-n] Input impedance at each electrode is similar.
RN-[26-n] Common mode disturbance is limited.
RN-[27-n] Must fit the rabbit's heart from AV to SA node for full spectrum analysis.
RN-[28-n] Electrodes must pick up at least recognizable signal for a heart rhythm.
RN-[29-g] Electrodes must void all interferences that may be introduced within the given environment.
RN-[30-n] Wire must be highly conductive
RN-[31-n] Gel must be highly conductive
RN-[32-n] Low impedance in the wire (less than 10 ohms/feet)
RN-[33-n] Gel must last long and be adhesive
RN-[34-n] Adhesive on gel must not damage heart when taking off electrode
RN-[35-n] Must last at least one trial (1 hour)
RN-[36-g] Multiple uses is possible without rebuilding.

5.2 Preamplifier and Filter Module (PFM) Requirements



The preamplifier and Filter Module will be responsible for receiving the acquired input data and constraining it to an amplified signal with minimal noise.

5.2.1 General Requirements

RN-[37-g] The PFM will operate within room temperature
RN-[38-n] The PFM will take input from a multiplexed signal of 9 channels

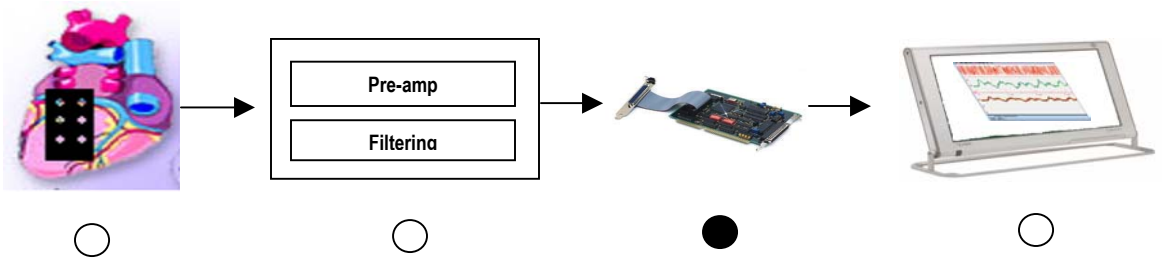
5.2.2 Physical Requirements

RN-[39-g] The PFM will be weigh < 500 grams
RN-[40-g] The PFM will be < 1 square foot in volume
RN-[41-g] Input (source) wires to PFM will be as short as possible

5.2.3 Performance Requirements

RN-[42-n] The PFM must have high input impedance
RN-[43-n] The PFM will be able to take real-time samples of input signals
RN-[44-g] The PFM will have a high amplification/gain
RN-[45-n] The PFM will implement a high frequency filter
RN-[46-g] The PFM will implement a low frequency
RN-[47-g] The PFM will have a high common mode rejection ratio
RN-[48-g] The PFM will require strong DC signal suppression

5.3 Analog Input Card Requirements



The analog input card acquires signals from the electrodes and converts them to digital information for further analysis at the computer.

5.3.1 General Requirements

RN-[49-n] The analog input card will have 16 single ended inputs.
RN-[50-n] The analog input card will operate from 0° to 50°C and 5% to 90% humidity.
RN-[51-g] The analog input card will have a programmable counter/timer.

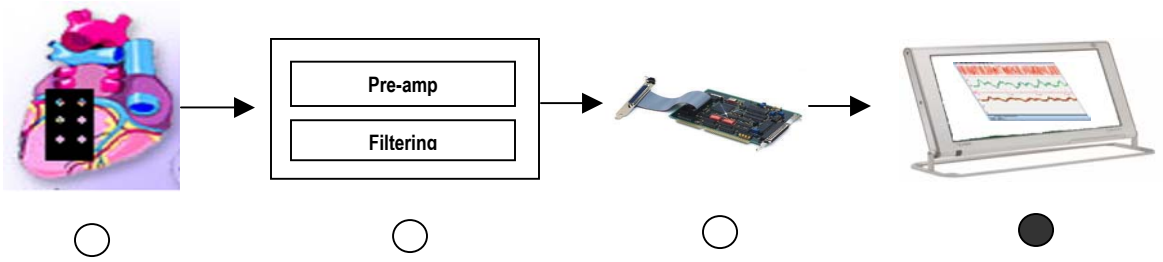
5.3.2 Physical Requirements

RN-[52-n] The analog input card will have a PCI-Bus compatible interface.
RN-[53-n] The analog input card will have a length of 7.5”.

5.3.3 Performance Requirements

RN-[54-n] The A/D converter will have a resolution of 12 bits.
RN-[55-n] The A/D converter will accept a range of uni-polar voltages
RN-[56-n] The A/D converter will accept a range of bipolar voltages
RN-[57-n] The conversion time of the A/D converter must be small (non noticeable to the human eye)
RN-[58-n] The A/D converter will have a high throughput of samples per second

5.4 Data Display Unit Requirements



The data display unit displays and saves the signal obtained by the needle probe array via the A/D converter.

5.4.1 General Requirements

RN-[59-n] Hardware: real-time data acquisition from A/D converter unit
RN-[60-n] Software: real-time display of signal acquired from A/D converter unit

5.4.2 Hardware Requirements

RN-[61-n] The PC will have an interface card that receives input from the A/D converter unit
RN-[62-n] The software should run on a Pentium III 800 MHZ processor with 128 MB of RAM or greater, running Windows 98/NT/2000.

5.4.3 Software and GUI Requirement

Figure 2 shows a high-level view of the program operation.

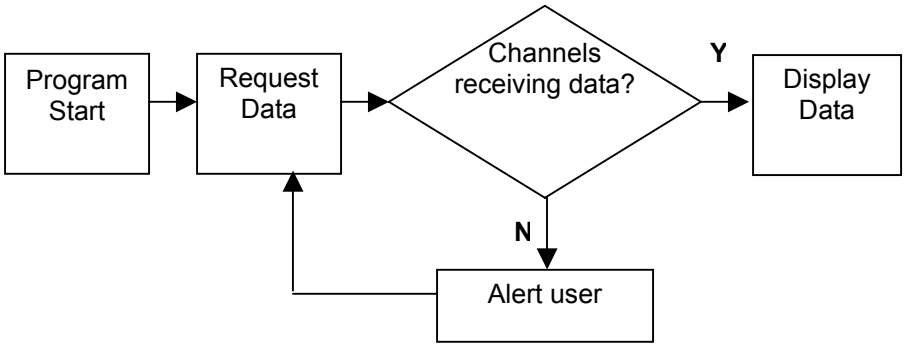


Figure 2: Block Diagram of Program Operation

RN-[63-n] The software will be a window-based program.

RN-[64-n]	The software will be able to graphically display the physical arrangement and activity (amount of signal measured) of each probe of the probe array .
RN-[65-g]	User can choose to view data acquired from each probe separately or viewed together on a same screen display.
RN-[66-n]	Easy to understand and navigation through all probe data display.
RN-[67-g]	The software will write the acquired data to an ASCII text file. The software will also be able to display previously saved data.
RN-[68-g]	User-friendly design GUI: essential functions such as data recording, saving and retrieval will be clear and easily accessible to the user.
RN-[69-n]	The software will be able to alert the user when any of the channel is not receiving any data (possibly detachment of the probe array, weak signal from the probe array, or malfunction of the A/D converter).
RN-[70-g]	The software will have a help menu will be available. It will attempt to troubleshoot problems for the user, and give a general overview of system capabilities.

6. System Test Plan

The *Avrio Small Heart EKG* is divided into three parts during the first phase of testing. The second phase of testing involves the improving of each individual parts and the examining of the whole system. The following sub-section describes these parts.

6.1 Testing Electrodes

- Nine electrodes are to be tested individually. One electrode is tested individually to ensure its workability while avoiding interference from the neighboring electrodes.
- Two electrodes are tested together, then four, eight, and finally all nine.
- Minimum distortion should be seen when increasing the number of electrodes used.

6.2 Testing Pre-Amplifiers and Filtering

- Signal is acquired and processed at the pre-amp and filtering module.
- The pre-amp and filtering module will first take in only 1 input signal at a time
- After it is verified that all electrode signals can be obtained with minimal noise and distortion, all nine electrode signals will be multiplexed into the pre-amp and filtering module
- The signal is tested and that maximum gain is achieved without clamping the signal

6.3 Testing Analog Input Card

- A signal will feed into the card and observe whether the output is expected.
- Signal display is accompanied by LabView.

6.4 Total System Test on a Rabbit Heart

- All parts are connected into one system.
- The electrode grid and the electrodes is placed on the rabbit heart.
- The DAQ card is placed on the PCI slot of the computer.
- User then observes the heart signal at the different part of the heart for arrhythmia detection. Signal display is done by LabView.

7. Standard Regulatory Requirements

The following standards are important to ensure that our device will not physically harm its intended subject. Canadian, American, and International standards are to be achieved in order for our device to be applicable to causes world wide.

7.1 Canadian Standards

- CAN/CSA C22.2 No. 601.2.25: Electrocardiographs safety parameters and requirements
- CAN/CSA C22.2 No. 601.2.27: Electrocardiographs Monitoring Equipment safety parameters and requirements
- Food and Drug Acts – Medical Device Regulations: Medical Device Regulations

7.2 American Standards

- US Food and Drug Administration Center for Devices and Radiological Health: regulation on health care products
- ANSI/AAMI EC11: safety and performance parameters for electrocardiographic systems
- ANSI/AAMI EC12: safety and performance parameters, test parameters and terminology for electrocardiographic electrodes
- ANSI/AAMI EC13: safety and performance parameters electrocardiographic heat rate and waveform monitors

7.3 International Standards

- IEC 60601 (1): Safety requirements, compatibility for medical electrical systems
- IEC 60601 (2): Safety, recording and analyzing of the electrographs
- ANSI/IEEE standards for health care facilities

8. Documentation

RN-[71-g] A technical user's manual will be provided in English and French

RN-[72-g] The user manual details step-by-step of the use of the *Avrio Small Heart EKG*

RN-[73-g] A service manual will be provided in English and French for repairman and technicians

RN-[74-g] Warranty will be included with the package

RN-[75-g] Contacts will be available with the package

9. Conclusion

This document contains the functional specifications for the *Avrio Small Heart EKG*. The functional spec contains detailed description of the design of the EKG machine. The building of the EKG will be done in separate phases corresponding to the way proposed in the document. The Avrio Medical group members will be separate into mainly 2 parts and tackle two different phases at the same time. The function spec of the *Avrio Small Heart EKG* will be a prototype for the eventual *Avrio Infant JET Heart Monitor*.

10. Reference

AAMI Standards (http://www.aami.org)

Canadian Standards Associations (http://www.csa.ca)

Institute for Electrical and Electronics Engineers (http://www.ieee.org)

International Electrotechnical Commission (http://www.iec.ch)

Standard Council of Canada (http://www.scc.ca/standards/index_e.html)

Underwriters Laboratories (http://www.ul.com)